

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of desellar amniotic membrane with wound debridement and its secondary closure on cesarean section wound infections(a Clinical Trials)

Protocol summary

Study aim

Comparison of the effect of desellar amniotic membrane with wound debridement and its secondary closure on cesarean section wound infections

Design

This is a randomized clinical trial study with a parallel design. This study is randomized, phase 2-3 study will be performed on 32 women undergoing cesarean section and referred to Imam Reza (AS) Hospital in 2020-2021 with a confirmed infection at the wound site. Simple random method are used for randomization and participants are assigned to two intervention groups.

Settings and conduct

This study, which will be performed in Imam Reza Hospital in Kermanshah, is non-blinded one. The amniotic membrane is transferred to the laboratory in the cold box

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients whose HIV test is negative; Informed consent Exclusion criteria: Patients with the positive hepatitis B and C test

Intervention groups

In the first intervention group, desensitized amniotic membrane is used which contains proteins, growth factors, and a matrix of the basal and decellularized membrane without any cell formation and pathogenesis. In the second intervention group, live and non-living tissue was separated from the wound in the operating room. If the debridement wound bleeds, the growth factor is released from the end of the released platelets and stimulates wound healing, in that case, the wound in the operating room will be closed again by a gynecologist. For both groups, 2 g of cefazolin, 50 mg of ranitidine, and 10 mg of metoclopramide for 10 days are administered intravenously in the morning until the fever has subsided.

Main outcome variables

Wound healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N186**

Registration date: **2022-06-01, 1401/03/11**

Registration timing: **prospective**

Last update: **2022-06-01, 1401/03/11**

Update count: **0**

Registration date

2022-06-01, 1401/03/11

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-04, 1401/03/14

Expected recruitment end date

2023-02-03, 1401/11/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of desellar amniotic membrane with wound debridement and its secondary closure on cesarean section wound infections(a Clinical Trials)

Public title
The effect of de sellar amniotic membrane on cesarean section wound infections

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients whose HIV test is negative Informed consent
Exclusion criteria:
Patients with the positive hepatitis B and C test

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple random method. 32 cards are selected and numbers from 1-32 are inserted on the cards. The cards are placed in an envelope. Two of the design partners take one card out of the envelope each time and announce the card number. Paired numbers are assigned to the intervention group and odd numbers to the control group

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah

University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Approval date
2022-03-13, 1400/12/22

Ethics committee reference number
IR.KUMS.MED.REC.1401.022

Health conditions studied

1

Description of health condition studied

cesarean

ICD-10 code

O90.0

ICD-10 code description

Disruption of cesarean delivery wound

Primary outcomes

1

Description

Wound healing

Timepoint

The first 48 hours and 7 days after the intervention

Method of measurement

By a doctor

Secondary outcomes

empty

Intervention groups

1

Description

In the first intervention group, desensitized amniotic membrane is used which contains proteins, growth factors, and a matrix of the basal and decellularized membrane without any cell formation and pathogenesis. 2 g of cefazolin, 50 mg of ranitidine, and 10 mg of metoclopramide for 10 days are administered intravenously in the morning until the fever has subsided.

Category

Treatment - Other

2

Description

In the second intervention group, live and non-living tissue was separated from the wound in the operating room. If the debridement wound bleeds, the growth factor is released from the end of the released platelets

and stimulates wound healing, in that case, the wound in the operating room will be closed again by a gynecologist. 2 g of cefazolin, 50 mg of ranitidine, and 10 mg of metoclopramide for 10 days are administered intravenously in the morning until the fever has subsided.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Valiyeh Mohammadi

Street address

Emam Reza Hospital, Parastar Boulevard

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Kermanshah

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Phone

+98 83 3427 6306

Email

Milad67669798@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Reza Khodarahmi

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Valiyeh Mohammadi

Position

Resident of Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Nasrin Jalilian

Position

Faculty member of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Valiyeh Mohammadi
Position
Resident of Obstetrics and Gynecology
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available